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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,811	07/11/2005	Bruce J. Gantz	22409-00113-US	3607

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EXAMINER	
WU, EUGENE TONG	

ART UNIT	PAPER NUMBER
3766	

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10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,811	GANTZ ET AL.	
	Examiner	Art Unit	
	Eugene T. Wu	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-10,12,13,22-25 and 36-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 8-10, 12, 13, 22-25, 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to:

07/09/2007 - Applicant response.
02/07/2007 - First non-final action.

Specification

1. The corrections submitted 07/09/2007 are sufficient to overcome the objections made in the previous Office Action.

Claim Objections

2. The amendments submitted 07/09/2007 are sufficient to overcome the objections made in the previous Office Action.

Claim Rejections - 35 USC § 112

3. The amendments submitted 07/09/2007 are sufficient to overcome the 112 rejections made in the previous Office Action.

Response to Arguments

4. Applicant's arguments, see Pages 10-12, filed 07/09/2007, with respect to the rejection(s) of claim(s) 1, 22, 38 have been fully considered and are persuasive. Therefore, the rejections has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 6, 8-10, 13, 22, 25, 36-39, 41-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (WO 00/69513) in view of Dutcher (US 5,153,090).

Regarding claims 1 and 9, Kuzma discloses the same invention as claimed, including an elongate carrier 12 (Figure 1A, 1B), a plurality of electrodes 14 in the carrier, and a stabilizing collar 18 adjacent to the carrier having an abutment surface 19 configured to abut a surface of the cochlea (Figure 2). Kuzma further discloses anchors 16 configured to prevent translation of the carrier along the longitudinal axis of the carrier. Kuzma does not disclose an anchor configured to prevent rotation. However, Dutcher teaches using a porous polyester fiber mesh (Col. 5, lines 29-31; Figure 5), in order to enhance tissue ingrowth to firmly fix the lead to target tissue (Col. 6, lines 26-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier.

Regarding claim 2, Kuzma discloses the collar having a first collar portion having a greater diameter than the carrier (Figure 1A).

Regarding claim 3, Kuzma discloses the distal end of the collar means 19 comprising the abutment surface (Figure 1A).

Regarding claim 4, Kuzma discloses the abutment surface extending at substantially a right angle to the carrier (Figure 1A).

Regarding claim 6, Kuzma discloses the collar means formed integrally with the carrier member (Figure 1A).

Regarding claim 8, Kuzma discloses the anchoring means extending adjacent the abutment surface (Figure 1A).

Regarding claims 10, Kuzma does not disclose mesh material molded within the collar. However, Dutcher further teaches including the mesh material with the collar of the lead, in order to insure a secure connection of the electrodes (Col. 5, lines 29-32; Figures 5 and 6). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the molding the mesh material with the collar of Dutcher with the device of Kuzma for the purpose of insuring a secure connection of the electrodes.

Regarding claim 13, Kuzma discloses the electrode array being insertable to a depth at the first basal turn of the cochlea (Figure 2).

Regarding claim 22, Kuzma discloses the same invention as claimed, including forming an opening into the cochlea (Page 8, lines 11-13; Figure 2), inserting the electrode array (Page 8, lines 13-21), and abutting a collar (Page 8, lines 16-21, 23-24). Kuzma further discloses securing the electrode array to prevent translation along a longitudinal axis of the array (Page 8, lines 21-24). Kuzma does not disclose securing the electrode array to prevent rotation. However, Dutcher

teaches using a porous polyester fiber mesh (Col. 5, lines 29-31; Figure 5), in order to enhance tissue ingrowth to firmly fix the lead to target tissue (Col. 6, lines 26-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier.

Regarding claim 25, Kuzma further discloses attaching the anchor to the recipient adjacent the formed opening (Page 8, lines 21-24).

Regarding claim 37, Kuzma further discloses halting insertion when the array is at the first basilar turn of the cochlea (Figure 2).

Regarding claims 38 and 39, Kuzma discloses the same invention as claimed, including means for abutting 19 (Figure 2), and means for anchoring 16 to prevent translation along the longitudinal axis of the array. Kuzma does not disclose a means for anchoring configured to prevent rotation. However, Dutcher teaches using a porous polyester fiber mesh (Col. 5, lines 29-31; Figure 5), in order to enhance tissue ingrowth to firmly fix the lead to target tissue (Col. 6, lines 26-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier.

Regarding claims 41-43, Kuzma further discloses the abutment surface sealing the opening in the cochlea (Figure 2; Page 8, lines 16-21).

5. Claims 12, 36, 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. (WO 00/69513) as applied to claim 1, and further in view of Kuzma (US 6,163,729).

Regarding claims 12, 36, 40, Kuzma '513 does not disclose an indicator means on the collar. However, Kuzma '729 teaches the use of an indicator 203 provided on the collar (Figure 2), for the purpose of preventing the electrode from being inserted too deep (Col. 6, line 65-Col. 7, line 17). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the indicator of Kuzma '729 with the device of Kuzma '513, in order to prevent the electrode from being inserted too deep. The Office notes that the indicator of Kuzma '729, being on the same side as the electrodes, as shown in Figures 2 and 10, is configured to indicate the rotational orientation of the electrode array. Kuzma '513 further discloses orienting the array during insertion (Page 7, lines 26-29).

6. Claims 23 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. (WO 00/69513) as applied to claim 22, and further in view of Knudsen et al. (US 4,487,210).

Regarding claims 23 and 24, Kuzma does not disclose fabricating a fascia washer and placing it over the electrode. However, Knudsen discloses fabricating a fascia washer from tissues from the head (Col. 2, lines 3-5), which is considered equivalent to Applicant's temporalis fascia harvested from recipient, and packing it around the lead, which is considered equivalent to placing it over the electrode array, for the purpose of anchoring the leads in place. Knudsen does not disclose placing the fascia washer over the electrode prior to insertion into the cochlea. However, it would have been obvious to place the fascia washer on the electrode prior to insertion since such a modification would have involved a mere change in sequence. A change in sequence is generally recognized as

being within the level of ordinary skill in the art. See Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959), In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the fabricating a fascia washer from temporalis fascia and placing it over the electrode array of Knudsen with the method of Kuzma, for the purpose of anchoring the electrode array in place.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eugene T. Wu whose telephone number is (571) 272-3109. The examiner can normally be reached on M-F: 9 AM - 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ETW
09/30/2007

Kristen Dosch Mullen

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